

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1654
	)	
DJURUP, et al.	)	Examiner: GUDIBANDE, S.
	)	
Serial No.: 10/524,434	)	Washington, D.C.
	)	
Filed: February 15, 2005	)	December 9, 2008
	)	
For: BACTERICIDAL, ANTI-	)	Docket No.: DJURUP=1
APOPTOTIC, PRO-	)	
INFLAMMATORY AND...	)	Confirmation No.: 4128

PETITION UNDER 37 CFR 1.181 FOR SUPERVISORY REVIEW

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Pursuant to 37 CFR 1.181, Applicants petition the Commissioner to review the examiner's Nov. 25 refusal to enter the after-final amendment filed Oct. 27, 2008. This is a no-fee petition.

The only change made by that amendment was to rewrite claim 74 as follows:

74. (Currently Amended) The peptide according to claim 1, wherein at least one of conditions (aa)-(dd) applies

- (aa) X19 is Arg,
- (bb) ~~X19~~ X9 is Pro,
- (cc) X19 is Gln and X1 includes Pro, or
- (dd) X19 is 2-5 amino acid residues.

**Reasons and Basis for the Amendment**

The October 27, 2008 amendment explained,

"The purpose of this amendment is to correct a typographical error in claim 74, proviso (bb), which recited "X19 is Pro", X9 having been intended. Claim 74 was presented in the December 2007

amendment, which explained at page 10, lines 8-9:

**"New claim 74 defines conditions (aa)-(dd)  
which are based solely on the pHBP (20-44)  
mutants.**

"The pHBP (20-44) mutants had previously been identified on page 8, lines 4-8 as sequences 593, 595-598 and 601-603, and the "reverse" sequence 599.

"It is evident from the table at pp. 8-9 of that amendment that these sequences exhibited Arg, Gln or the pentapeptide PRGQK at X19, but not just the Pro recited by claim 74 (bb). However, for X9, those sequences exhibit either Pro or Ala, but Ala is found at X9 in the prior art reference Pereira. Hence, X9=Pro was clearly the intent of claim 74(bb). Correction of this error puts the claim in better form for consideration on appeal and thus satisfies 37 CFR 41.33(a) and MPEP 1206(I)(C).

"Correction is necessary since otherwise the PTO would need to reopen prosecution to consider the overlooked written description issues raised by uncorrected clause (bb) of claim 74, i.e., basis for recitation of "X19 is Pro". The amendment was not earlier presented since Counsel only discovered the error while drafting the Appeal Brief. Hence, the amendment is also proper under 37 CFR 41.33 and MPEP 1206(I)(D)."

It is clear from the boldfaced passage that "X19 is Pro" could not have been intended. While there is disclosure that X19 can be any group 5 residue, and Pro is one of the 17 such residues, X19 is not Pro in **any** of the sequences specifically

disclosed by applicants, let alone in the hBP(20-44) mutants on which claim 74 was supposed to be "solely based".

In contrast, "X9 is Pro" is supported by the hBP(20-44) mutant sequences 593, 597, 598, 600, 601, 602, and 603, as evident from the aforementioned table in the December 2007 amendment.

Moreover, it should be inferred that "X9 is Pro", rather than X19 is some other amino acid, was intended. As previously explained, the only possibilities for X19 which are "solely based on the hBP(20-44) mutants" are Arg, Gln, and the pentapeptide PRGQK. However, X19 is Arg is already covered by (aa), X19 is Gln is already covered by (cc), and X19 being a pentapeptide is already covered by (dd).

We would add that it is evident that "X9 is Pro" was intended because of the clear parallelism between the provisos (a)-(d) of claim 1 and (aa)-(dd) of claim 74:

Claim 1 provisos (a)-(d)		Claim 74 provisos (aa)-(dd)	
1a	X19 is Arg or Ala	74aa	X19 is Arg
1b	X9 is Pro, Arg, or Gln	74bb	<del>X19</del> <u>X9</u> is Pro
1c	X19 is Gln and X1 includes Pro	74cc	X19 is Gln and X1 includes Pro
1d	X19 is 2-5 amino acid residues	74dd	X19 is 2-5 amino acid residues

It can be seen from the table that 74(cc) is identical to 1(c), 74(dd) identical to 1(d), and 74(aa) more limiting than 1(a). It would therefore be expected that 74(bb) would be identical to, or more limiting than 1(b).

#### Relevant Chronology

A final office action was mailed March 19, 2008, and a notice of appeal, with a request for pre-appeal brief

conference, was filed on September 19, 2008. The PABC panel decision, advising us to proceed with the appeal, was mailed on October 2, 2008.

In the course of preparing the appeal brief, which was prepared in accordance with the "old rules" (pre-Dec. 10), counsel discovered a typographical error in claim 74, and on October 27, 2008, filed the amendment at issue to correct that error.

On Nov. 10, 2008, Counsel asked Examiner Gudibande concerning the status of the amendment and was told that he needed to consult with his SPE. On Nov. 13, 2008, not having heard back from Examiner Gudibande, Counsel contacted the SPE, Cecilia Tsang, and explained the nature of the amendment, the reason for considering the language to be in error, and the reason that the examiner could fairly infer that the proposed amended language was what had been intended. Tsang told Counsel that she would enter the amendment.

Counsel's staff continued to monitor PAIR. On Nov. 19, 2008, since no advisory action had yet appeared, Counsel called Tsang again. Tsang informed him that the amendment had been entered on Nov. 13, as promised. In support of this, PAIR did show a status date of Nov. 13.

In reliance on Tsang's representations, Counsel finalized the draft of the appeal brief, assuming the entry of the amendment to claim 74. However, Counsel held back on filing the appeal brief, pending the appearance of the advisory action in PAIR.

On Dec. 1, a check on PAIR revealed that an advisory action which **refused** entry of the amendment had been signed on Nov. 25 by primary examiner Kovar. Counsel contacted Kovar, Gudibande, and Tsang, but did not receive a promise that the Nov. 25 advisory action would be vacated and a new advisory action, entering the amendment, mailed.

On Dec. 5, 2009, examiner Gudibande orally advised counsel that prosecution would be reopened and a new action

mailed. If prosecution is reopened, the questioned amendment will be entered as a matter of right, which will moot this petition. However, as of Dec. 9, 2009, despite two requests, Counsel had not received anything in writing from the PTO.

Hence, this Petition is filed.

#### **Legal Standard**

37 CFR 41.33(a) states that "amendments filed after the date of filing an appeal ... and prior to the date a brief is filed ... may be admitted as provided in Sec. 1.116...."

37 CFR 1.116(b)(2) states that "an amendment presenting rejected claims in better form for appeal may be admitted." Clearly, the correction of an evident typographical error places the claims in better form for appeal.

Moreover, it is clear that since the issue is one of written description, and the present "X19 is Pro" language is supported only by the generic definition of X19 as a group 5 residue, whereas the proposed "X9 is Pro" language is supported not only by the generic definition of X9, but also by the specific hBP(20-44) mutant sequences 593, 597, 598, 600, 601, 602 and 603, that the amended claim 74 is, at least on the basis of the interpretation of written description standards argued by applicants, in better condition for appeal.

37 CFR 1.116(b)(3) states that "an amendment touching the merits ... may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented." The amendment is necessary because, if the amendment is not entered, claim 74 will not in fact present provisos which, as argued when that claim was first presented, are solely based on the disclosed hBP(20-44) mutants. The amendment was not earlier presented because the applicants (and counsel) did not become aware of the error until counsel undertook the drafting of the appeal brief.

MPEP 714.13(II) indicates that a refusal to enter should not be arbitrary. In the November 25, advisory action, the examiner indicates that the bases for refusing to enter the amendment are

- (1) it "raises the issue of new matter", and
- (2) it presents "new issues requiring further consideration and/or search".

With regard to the first point, to "raise" an issue, the issue must not exist previously. The claims were already rejected on written description (new matter) grounds. The rejection was applied to claim 74, but only the limitations of claim 1 were discussed. Those limitations included proviso (b), "X9 is Pro, Arg, or Gln". The examiner has taken the position that as a matter of law, applicants cannot disclaim an embodiment merely because it was positively recited. While we disagree with the examiner's position, the examiner's rationale for holding this proviso to lack written description would apply equally to the proposed amended proviso (bb) of claim 74, i.e., "X9 is Pro".

Thus, the amendment doesn't "raise" any issue that wasn't already present and considered.

Likewise, the amendment doesn't require further consideration and/or search. The claims have been held free of the prior art. There is no need to search a dependent claim if the base claim is already known to be free of the prior art, since the dependent claim is necessarily narrower than the base claim.

As to consideration, the examiner didn't previously give specific consideration to claim 74 at all, perhaps because his rationale for the rejection of 1 was a general denial of written description for the disclaimer of disclosed embodiments, and hence the amendment of proviso (bb) doesn't

require that the examiner "reconsider" claim 74.

Moreover, in the request for pre-appeal brief conference, section 4, applicants specifically argued the basis for each of the three possible options for X9 in the proviso (b) of claim 1, including X9=Pro, and thus the office, in considering that request, has already given consideration to an X9=Pro limitation.

It is therefore respectfully urged that the PTO should vacate the Nov. 25 advisory action, and enter a new advisory action (which enters the amendment but maintains the rejection), so that the appeal can proceed with "clean" claims.

#### **Miscellaneous**

While the PTO is addressing this case, we wish to note a defect in the final rejection. The final rejection mailed March 19, 2008 indicated that claim 73 was pending, and that the rejection of claim 73 under 35 USC 102 had been withdrawn, but did not list it as rejected under the written description requirement. Since claim 73 is drawn to

A pharmaceutical composition comprising a  
peptide as defined in claim 1

and claim 1 is so rejected, we believe the examiner intended to include it in the rejection.

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However, the PTO might wish to clarify the record by issuing a supplemental action.

Respectfully submitted,

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## Appendix

The pertinent portions of the base claim 1 are as follows:

1. (Previously Presented) A peptide having a sequence of at most 44 amino acid residues comprising a motif of the formula

X<sup>1</sup> - X<sup>2</sup> - C y s - X<sup>3</sup> -  
X<sup>4</sup>-X<sup>5</sup>-X<sup>6</sup>-X<sup>7</sup>-X<sup>8</sup>-X<sup>9</sup>-X<sup>10</sup>-X<sup>11</sup>-X<sup>12</sup>-X<sup>13</sup>-X<sup>14</sup>-X<sup>15</sup>-X<sup>16</sup>-X<sup>17</sup>-Cys-X<sup>18</sup>-X<sup>19</sup>,

wherein

(1) each of X<sup>1</sup> and X<sup>19</sup> is, independently, either a sequence consisting of 2-5 amino acid residues or a single amino acid residue, and

(2) each of X<sup>2</sup>-X<sup>18</sup> is, independently, a single amino acid residue, and

wherein ...

X<sup>9</sup> is selected from Group 5...

X<sup>19</sup> is a sequence consisting of 2-5 amino acid residues, or a single amino acid residue selected from Group 5...

Group 5 consisting of Ala, Asn, Arg, Gln, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr, and Val;

with the proviso, that when X<sup>1</sup> includes Pro, then X<sup>19</sup> is Gln, and wherein at least one of the following conditions applies:

- (a) X<sup>19</sup> is Arg or Ala,
- (b) X<sup>9</sup> is Pro, Arg, or Gln,
- (c) X<sup>19</sup> is Gln and X<sup>1</sup> includes Pro,
- (d) X<sup>19</sup> is 2-5 amino acid residues, or
- (e) X<sup>10</sup> is Asn or Gln.